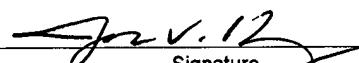




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<b>PRE-APPEAL BRIEF REQUEST FOR REVIEW</b>		Docket Number (Optional) <b>ACSG 58267 (1700X)</b>
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<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s).</p> <p>Note: No more than five (5) pages may be provided.</p>		
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.  <b>John V. Hanley</b> Signature</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>38,171</u> <b>310-824-5555</b> Telephone number</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____ <b>April 7, 2006</b> Date</p>		
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>		
<p><input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.</p>		

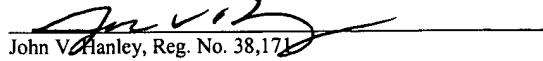
This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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John V. Hanley, Reg. No. 38,171

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 09/470,874  
Applicant : Marc M. Jalisi et al.  
Filed : December 22, 1999  
Title : COMPOSITE GUIDEWIRE WITH DRAWN  
AND FILLED TUBE CONSTRUCTION  
Art Unit : 3763  
Examiner : Mark K. Han  
  
Docket No.: : ACGS-58267 (1700X)  
Customer No. : 24201

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PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates generally to an elongate medical device such as a guide wire. More particularly, the presently claimed invention is directed towards a heat treated elongate member or a guide wire including a composite elongate core, the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a layer formed of a superelastic material. The present application teaches that a "significant aspect of the invention resides in forming the composite elongate core member 11, at least in part, from precipitation hardenable material so that the ultimate tensile strength ( $\sigma_{uts}$ ) and tensile yield strength ( $\sigma_{ys}$ ) of the composite (FIG. 4) are raised to enhance the elastic strength and

operability of the guide wire, as compared to the elongate core member formed of superelastic NiTi alone."

#### NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of January 11, 2006 is being filed concurrently herewith along with the appropriate fee. Authorization is provided to charge our deposit Account No. 06-2425 any additional fees that may be due in connection with this filing.

#### ISSUES ON APPEAL

At issue is whether claims 1-8, 13-15, 17, 19, 20 and 22-27 were properly rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,636,641 to Fariabi. Additionally, at issue is whether claims 9-12 were properly rejected under § 103(a) as being unpatentable over Fariabi in view of U.S. Patent No. 5,916,166 to Reiss et al. It is to be noted that pending claims 21, 28 and 29 were objected to as being dependent upon a rejected base claim but were deemed allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. A copy of the pending claims is attached hereto as Exhibit A. A copy of the drawings is attached hereto as Exhibit B. The Fariabi patent is attached hereto as Exhibit C and a copy of the Reiss et al. patent is attached hereto as Exhibit D.

#### ARGUMENT

In the final Office action dated January 11, 2006, the Examiner stated that the Fariabi patent discloses an elongate member 10, elongate core 11, inner core 13, outer layer 12 and flexible body 14 but that Fariabi does not disclose "a superelastic outer layer and a precipitation hardened inner core." The Examiner then concluded that "it would have been an obvious matter

of design choice to a person of ordinary skill in the art to rearrange the materials of the inner core and outer layer because Applicant has not disclosed that having a superelastic outer layer with a precipitation hardened inner core provides an advantage, is used for a particular purpose, or solves the stated problem." The Examiner then further stated that one of ordinary skill in the art "would have expected Applicants invention to perform equally well with the superelastic inner core and outer core layer of precipitation hardened material because both would exhibit properties of both materials." The Examiner finally concluded that it would have been an obvious matter of design choice to modify Fariabi to obtain the invention as specified in claims 1-8, 13-15, 17, 19, 20 and 22-27.

In formulating the final rejection of the claims, the Examiner set forth the requirements of § 103(a) which include making a determination that "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains." It is respectfully submitted, however, that by missing key disclosure set forth in the present application, the Examiner has improperly minimized the differences between the subject matter recited in the claims and the cited art.

Significantly, the Examiner has based the § 103(a) rejection of the claims upon the proposition that the "Applicant has not disclosed that having a superelastic outer layer with a precipitation hardened inner core provides an advantage, as used for a particular purpose, or solves a stated problem" because after stating such, the Examiner made an assessment concerning what one of ordinary skill in the art would do and then concluded that modifying the teachings of the cited art would have been obvious to one of ordinary skill in the art. Therefore, in characterizing the present application as lacking in disclosure regarding the recited

precipitation hardened core and outer layer of superelastic material, the Examiner believed there to be little difference between the subject matter recited in the claims and the prior art.

It is to be noted, however, that the specification for the present matter does indeed disclose reasons for providing an elongate member or guide wire with a composite elongate core including inner core formed of the precipitation hardened material and a layer of superelastic material arranged concentrically about the inner core. That is, as stated at page 12, line 14 et seq., the present application states "a significant aspect of the invention resides in forming the composite elongate core member 11, at least in part, from precipitation hardenable material so that the ultimate tensile strength ( $\sigma_{uts}$ ) and tensile yield strength ( $\sigma_{ys}$ ) of the composite (FIG. 4) are raised to enhance the elastic strength and operability of the guide wire, as compared to an elongate core member formed of superelastic NiTi alone."

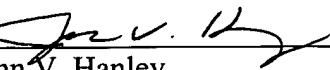
Therefore, the Applicant has not only disclosed that having a superelastic outer core with the precipitation hardened inner core provides "an advantage, as used for a particular purpose, or solves the stated problem" but the Applicant also provides a basis that one of ordinary skill of the art would not conclude that the Applicant's invention would perform equally as a structure formed from a superelastic inner core and an outer layer of a precipitation hardenable material. Thus, it is respectfully submitted that it would not have been an obvious matter of design choice to modify the teachings of the Fariabi patent to meet the limitations recited in independent claims 1, 8, 26 and 27 and their respective dependent claims.

Therefore, it is respectfully submitted that the Fariabi patent does not render obvious pending claims 1-8, 13-15, 17, 19, 20 and 22-27. Due to their dependency upon independent claim 8, it is also respectfully submitted that claims 9-12 are not obvious as being unpatentable over Fariabi in view of Reiss et al. Accordingly, the Appellants respectfully request that the

rejections of claims 1-15, 17, 19, 20 and 22-27 be withdrawn and that each of pending claims 1-15, 17 and 19-29 be passed to issue.

Respectfully submitted,

FULWIDER PATTON LLP

By:   
John V. Hanley  
Registration No. 38,171

JVH:kst

Howard Hughes Center  
6060 Center Drive, Tenth Floor  
Los Angeles, CA 90045  
Telephone: (310) 824-5555  
Facsimile: (310) 824-9696  
Customer No. 24201  
120615.1

U.S. PATENT APPLICATION NO. 09/470,874  
COMPOSITE GUIDEWIRE WITH DRAWN AND FILLED TUBE CONSTRUCTION  
Inventors: M. M. Jalisi; D. M. Anderson; W. E. Cornish; N. A. Nicotra; M. T. Richardson  
ACS Ref. No. 1700X; our Docket No. ACSG-58267

Pending Claims

1. (Previously presented) A heat-treated elongate member, comprising:  
a composite elongate core;  
the composite elongate core including an inner core formed of a precipitation hardened material and a layer formed of a superelastic material;  
wherein the layer is arranged concentrically about the inner core.
2. (Original) The elongate member of claim 1 wherein the composite elongate core has a modulus of elasticity of at least  $9 \times 10^6$  psi.
3. (Original) The elongate member of claim 2 wherein the modulus of elasticity is at least  $12 \times 10^6$  psi.
4. (Original) The elongate member of claim 3 wherein the modulus of elasticity is at least  $15 \times 10^6$  psi.
5. (Original) The elongate member of claim 1 wherein the composite elongate core has an ultimate tensile strength of at least 150 ksi.
6. (Original) The elongate member of claim 5 wherein the ultimate tensile strength is at least 180 ksi.
7. (Original) The elongate member of claim 6 wherein the ultimate tensile strength is at least 200 ksi.
8. (Previously presented) A heat-treated elongate member, comprising:  
a composite elongate core;  
the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a first layer formed of a superelastic material and having a proximal section and distal section;  
a flexible body at least partially overlying the distal section; and  
wherein the precipitation hardenable material comprises at least two materials selected from the group consisting of nickel, cobalt, molybdenum, chromium, tungsten, and iron.

9. (Previously presented) The elongate member of claim 1 wherein the precipitation hardenable material is precipitation hardenable stainless steel.
10. (Original) The elongate member of claim 9 wherein the precipitation hardenable material is chromium-nickel based single stage martensitic precipitation hardenable stainless steel.
11. (Original) The elongate member of claim 9 wherein the precipitation hardenable stainless steel is essentially nickel free.
12. (Original) The elongate member of claim 9 wherein the precipitation hardenable stainless steel includes less than about 1% nickel.
13. (Original) The elongate member of claim 8 wherein the precipitation hardenable material is a cobalt based precipitation hardenable alloy.
14. (Original) The elongate member of claim 13 wherein the cobalt based alloy further includes nickel, molybdenum and chromium.
15. (Original) The elongate member of claim 14 wherein the alloy further includes less than about 10% by wt. iron.
16. (Cancel)
17. (Previously presented) The elongate member of claim 8 wherein the inner core and the first layer are independently formed.
18. (Cancel)
19. (Previously presented) The elongate member of claim 17 wherein the first layer is formed from superelastic NITINOL.
20. (Previously presented) The elongate member of claim 19 wherein the composite elongate core further includes a second layer disposed at least in part concentrically about the first layer and formed from a material similar to the inner core material.
21. (Previously presented) The elongate member of claim 8 wherein the composite elongate core further includes a second layer portion disposed at least in part about the first layer portion and formed from a material similar to core element material.
22. (Previously presented) The elongate member of claim 8 wherein the elongate member is a guidewire.

23. (Original) The elongate member of claim 22 wherein the composite elongate core includes a distal segment having a distally tapered section with proximal and distal portions, and a distal flexible section, the inner core element being at least partially exposed at the distal flexible section of the distal segment of the composite elongate member.

24. (Original) The elongate member of claim 19 wherein the elongate member is a guidewire.

25. (Original) The elongate member of 24 wherein the composite elongate core includes a distal segment having a distally tapered section with proximal and distal portions, and a distal flexible section, the inner core element being at least partially exposed at the distal flexible section of the distal segment of the composite elongate member, and the first layer portion being at least substantially exposed at the proximal portion of the distally tapered section of the distal segment of the composite elongate core.

26. (Previously presented) A guide wire, comprising:

a composite elongate core;

the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a layer formed of a superelastic material and having a proximal section and distal section;

a flexible coil disposed at a distal end of the distal section;

wherein the precipitation hardened material and superelastic material extend from the proximal section to at least through a part of a length of the flexible coil.

27. (Previously presented) A heat-treated elongate member, comprising:

a composite elongate core;

the composite elongate core including an inner core formed of a precipitation hardened material concentrically surrounded by a layer formed of a superelastic material and having a proximal section and distal section;

a flexible body disposed at a distal end of the distal section;

the distal section having a proximal portion and a tapered distal portion; and

wherein the precipitation hardened material and superelastic material extend from the proximal section of the elongate core to the tapered distal portion of the distal section of the elongate core and continuing through at least a part of a length of the flexible body.

28. (New) The heat-treated elongate member of claim 1, further comprising a second layer concentrically arranged about the layer formed of the superelastic material.

29. (New) The heat-treated elongate member of claim 28, wherein the second layer is formed of the precipitation hardened material.

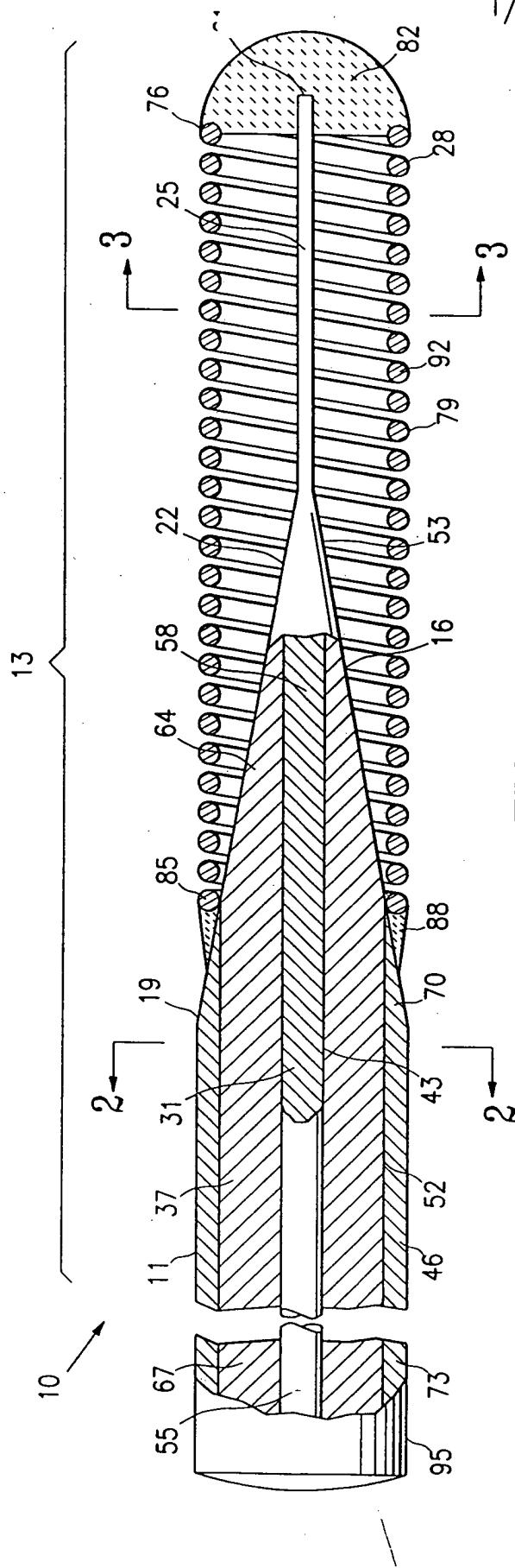


FIG. 1

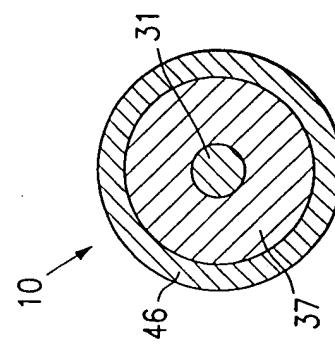


FIG. 2

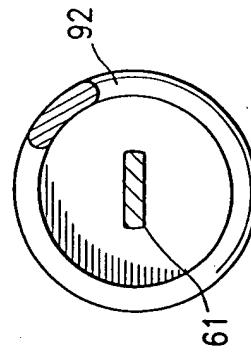


FIG. 3

FIG. 5

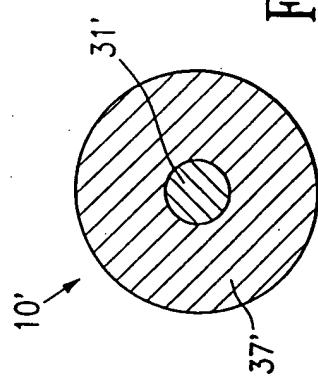


FIG. 6

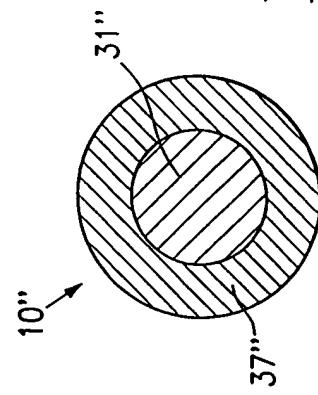


FIG. 4

